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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,436	07/23/2002	Istvan Szelenyi	033285-009	6934

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EXAMINER	
COOK, REBECCA	
ART UNIT	**PAPER NUMBER**
1614	9

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,436	Applicant(s) SZELENYI ET AL.	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The English language translation of international application No. PCT/EP00/09391 was not received.

The specification is objected to under 37 CFR1.71 because it is not clear in the specification that allergic rhinitis is a condition that is distinct from rhinoconjunctivitis. See page 1, line 10, page 2, lines 1-2 and page 2, lines 14-21 where "rhinoconjunctivitis" is placed in parentheses following "allergic rhinitis."

Claims 1-9, 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification on page 1 and page 3 disclose that the claimed composition and method are intended for local treatment, the broad claims do not recite this limitation. Furthermore, page 4 discloses that "topically" means intranasally or intraocularly. It is clear from the disclosure on pages 2-3 that loteprednol is not intended to be administered orally.

Claims 5-9, 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating rhinoconjunctivitis, does not reasonably provide enablement for all disorders of the lower and upper airway or for the treatment of all allergies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no one treatment that is used for all

of these disorders, which would include, but not be limited to, cancer, bacterial, viral and fungal infection and black and brown lung disease.

Claims 1-9, 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 4, 9 and 11 the phrase "pharmaceutically tolerable ester" is colloquial and is not clear. Amending the phrase to recite "pharmaceutically acceptable ester" will overcome this rejection.

In claims 3, 5 and 9 the phrase "and/or" is confusing as to what is being claimed. In re Anderegg 51 USP 66.

In claims 6 and 9 it is not clear if the patient is required to have more than one disorder. Amending the claims to recite "disorder" will overcome this rejection.

In claim 6 the word "such" renders the intent of the claim confusing. Amending the claim to recite "said" will overcome this rejection.

In claims 6-8 it is not clear that loteprednol and the antihistamine are administered simultaneously, sequentially, separately or independently of one another.

Claims 7 and 8 do not further limit claim 5 from which they depend. Claim 5 recites a topically administerable antihistamine, but claim 7 recites that the method is administered as an inhalable liquid and claim 8 recites that the method is administered orally.

In claims 5 and 9 it is not clear how treatment of allergies distinguishes over disorders of the lower and upper airways, since disorders of the lower and upper airways include allergies, and the specification does clarify this.

In claim 9 it is not clear how the loteprednol and the antihistamine(s) are mixed "individually."

In claim 11 it is confusing as to whether two distinct conditions are claimed. The specification is confusing as to whether allergic rhinitis is a condition that is distinct from rhinoconjunctivitis. See page 1, line 10, page 2, lines 1-2 and page 2, lines 14-21 where "rhinoconjunctivitis" is placed in parentheses following "allergic rhinitis."

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlaender.

Friedlaender (pages 54-55) disclosed that antihistamines including levocabastine, azelastine and other antihistamines are used as topical therapy for allergic conjunctivitis. Friedlaender (pages 56-57) further discloses that corticosteroid eyedrops, including loteprednol etabonate are used to treat allergic conjunctivitis

The instant composition and method differ over Friedlaender in claiming a composition comprising both loteprednol and an antihistamine and a method in which the loteprednol are administered simultaneously, sequentially or separately. However,

in the absence of a showing of unexpected results it would be obvious to one of ordinary skill in the to combine loteprednol and an antihistamine, since both are taught in the art to be useful to treat allergic conjunctivitis.

Claim 7 recites the limitation solid preparation. Claim 8 recites the limitation oral administration. However, Friedlander (page 55, left column) discloses that oral antihistamines are effective to treat allergic conjunctivitis. In the absence of a showing of unexpected results it would be obvious to administer the antihistamine orally in the instant method, since Friedlander discloses that oral antihistamines are effective against allergic conjunctivitis. Furthermore, it would be obvious that the oral antihistamine could be a solid preparation, since solid forms of antihistamines are well-known in the pharmacy art.

Claims 1-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 709 099 in view of WO 97/01337. '099 (page 4) discloses that loteprednol etabonate is used in the treatment of allergic rhinitis.

The claims differ over '099 in reciting that the loteprednol is administered with an antihistamine and that the method is administered as a solid preparation (claim 7) and orally (claim 8).

However, '337 (page 1, lines 19-35, pages 2-4) discloses that oral and topically administered antihistamines, including azelastine and levocabastine, are useful to treat allergic rhinitis. Therefore, in the absence of a showing of unexpected results it would be obvious to one of ordinary skill in the to combine loteprednol and an antihistamine, since both are taught in the art to be useful to treat allergic rhinitis.

Furthermore, it would be obvious that the oral antihistamine could be a solid preparation, since solid forms of antihistamines are well-known in the pharmacy art.

It is noted that Tables 1 and 2 on pages 5 and 6 show unexpected results for a composition comprising azelastine and loteprednol together and in a method of using said composition to treat rhinorrhea.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

REBECCA COOK
PRIMARY EXAMINER
GROUP 1299/1614

July 23, 2003